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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,367	12/09/1998	ULF SCHRODER	REF/SCH29644	1613

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BACON & THOMAS
625 SLATERS LANE
4TH FLOOR
ALEXANDRIA, VA 223141176

EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/147,367	Applicant(s) Schroder
	Examiner Gollamudi Kishore	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 24, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *65-91* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *65-91* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The request for the extension of time and amendment filed on 12-24-02 are acknowledged.

Claims included in the prosecution are 65-91.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 65-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 65 recites only a combination of a monoglyceride and a fatty acid and no antigen; yet the last two lines of claim 65 recite "elicits an immune response when administered to an animal". It is unclear as to how a combination of a monoglyceride and fatty acid would elicit an immune response without an antigen.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 65-76, 78-82 and 84-89 are rejected under 35 U.S.C. 102(b) as being anticipated by Isaacs (4,997,851).

Isaacs discloses a composition containing monoglycerides and free fatty acids (note the abstract, columns 9-12 and claims). One of the forms for the composition is an emulsion and therefore, the presence of water is implicit. The reference teaches in vitro studies wherein the composition is incubated with a virus (Table 3) and therefore, meets the requirements of instant claims which recite the presence of antigen.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Isaacs teaches either monoglycerides or fatty acids and does not teach the combination of the two. This argument is not persuasive since on col. 9, lines 6-9, Isaacs teaches "fatty acids and/or monoglycerides thereof". This implies a combination. With regard to the amounts of each component, the ratios calculated from the individual amounts of each in the Tables 2 and 3 appear to fall within the limits of instant broad ratios.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 65-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/06921 by itself in combination with Amselem (5,716,637), Wright (5,730,989), Koga (5,352,450), Carrano (5,739,118) individually or in combination.

As pointed out before, WO discloses formulations containing monoglyceride preparation. The preparation contained 98.8% monoglycerides and 1 % free fatty acids. The composition is for the delivery of vaccines (note page 20, lines 25-30, pages 45-47 and claims). What is lacking in WO is the addition of a fatty acid in addition to what is already present in the monoglyceride preparations.

Amselem teaches oleic acid as one of the components for the delivery of vaccine formulations (note the examples).

Wright while teaching oral vaccine formulations teaches oleic acid as one of the components (note col. 4, lines 11-22).

Koga similarly teaches oleic acid as one of the components in vaccine formulations for preventing dental caries (col. 20, line 59 et seq.).

Carrano teaches oleic acid is a preferred as a genetic vaccine facilitator (col. 14, lines 6-51).

It would have been obvious to one of ordinary skill in the art to add oleic acid in the formulations of WO with the expectation of obtaining at least an additive effect or the best possible results since the references Amselem, Wright, Koga and Carrano each teach that oleic acid is used in vaccine preparations as an adjuvant.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO discloses a fragmenting agent in addition and instant adjuvant does not contain a fragmenting agent. This argument is not found to be persuasive since although instant claims recite 'consisting essentially of', a closer examination of the specification indicates that other material can be present in the composition. Furthermore, instant monoglyceride preparation itself is not pure and contains other material. Applicant argues that applicant's adjuvant comprises at least 2 % fatty acid which distinguishes over WO. This argument is not found to be persuasive since by increasing the amount of fatty acid by one percent, applicant has not shown any unexpected results. The examiner also points out page 7, lines 20-22 of the specification where applicant states "when monoglycerides and fatty acids are formulated together the percent ratio of monoglyceride in fatty acid may be varied between 1 to 99 %---". This includes even 1 % of fatty acid and indicates no criticality for this component. In addition,

the examiner points out that instant specification contains no data showing the effect of the monoglyceride, fatty acids by themselves, to compare with the combination of the two.

Applicant's arguments that the secondary references do not teach a combination of monoglyceride and the fatty acid are not persuasive since these references show that oleic acid is an essential component in vaccine preparations. Therefore, it is still the examiner's position that one of ordinary skill in the art would be motivated to add oleic acid in WO with the expectation of obtaining the best possible effect. Applicant's arguments that Amselem contains at least 5 other components besides oleic acid and Wright, Koga and Carrano also contain other additives are not found to be persuasive since these references are combined for their teachings of fatty acids. Furthermore, as pointed out above, instant specification also indicates the addition of other components and the monoglyceride itself contains other components.

7. Claims 65-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/06921 by itself in combination with Amselem (5,716,637), Wright (5,730,989), Koga (5,352,450), Carrano (5,739,118) individually or in combination as set forth above, further in view of Isaacs cited above.

The teachings of WO, Amselem, Koga, Wright and Carrano have been discussed above. As discussed above, Isaacs teaches the effectiveness of the combination of a monoglyceride and a fatty acid against viruses.

One of ordinary skill in the art would be further motivated to add a fatty acid to the formulations of WO since fatty acids are also effective against the viruses as taught by Isaacs.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments with regard to WO, Amselem, Wright, Koga and Carrano have been addressed above. Applicant argues that Isaacs only teaches the use of monoglycerides or fatty acids. This argument is not found to be persuasive since on col. 9, lines 6-9, Isaacs teaches "fatty acids and/or monoglycerides thereof". This implies a combination.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

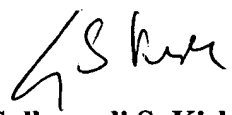
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a

properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

April 1, 2003